UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01- 12257-PBS** **Subcategory Case. No. 06-11337**
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Dey, Inc., et al.*, Civil Action No. 05-11084-PBS	**Hon. Patti B. Saris** **Magistrate Judge Marianne B. Bowler**

DEFENDANTS DEY, INC., DEY PHARMA, L.P., AND DEY L.P., INC.'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO EXCLUDE THE OPINIONS OF MARK DUGGAN, PH.D.

Dated: March 22, 2010

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PRELIMINARY STATEMENT

Defendants Dey Pharma, L.P. (formerly known as Dey, L.P.), Dey, Inc., and Dey L.P., Inc. (collectively "Dey"), submit this memorandum of law in support of their motion to exclude the opinions and testimony of Mark Duggan, Ph.D., designated by Plaintiffs the United States and Ven-A-Care of the Florida Keys, Inc. (collectively, "Plaintiffs") as their expert witness.

Plaintiffs in this False Claims Act case seek single damages of approximately $363 million based entirely on the opinions and calculations of their expert, Mark Duggan, Ph.D. It is axiomatic that Dr. Duggan's expert testimony cannot be presented to the jury unless Plaintiffs first meet the heavy burden to establish that Dr. Duggan's calculations and related opinions are: i) the product of reliable principles and methods; ii) based on relevant and properly tested data; and iii) not based on improper assumptions that would render his testimony speculative. Plaintiffs utterly fail to meet their burden on each of these factors, let alone all of them. Dey does not challenge or question Dr. Duggan's qualifications as an expert economist with a background in health care and an impressive resume. Indeed, it is precisely because he is a qualified economist that it would be particularly prejudicial to Dey for the jury to hear Dr. Duggan present opinions that, as shown below, are entirely unreliable and fail to meet the standards under Fed. R. Evid. 702. Accordingly, Dr. Duggan cannot be permitted to testify and his opinions must be excluded.

LEGAL STANDARD

Plaintiffs have the burden of establishing the admissibility of Duggan's testimony. *U.S. ex rel. Loughren v. UnumProvident Corp.*, 604 F. Supp. 2d 259, 265 (D. Mass. 2009). Expert testimony of a qualified witness is admissible only "if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the

witness has applied the principles and methods reliably to the facts of the case." Fed. R. Evid. 702. The goal of an inquiry under *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993) is "to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *137 Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999); *see also Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 318 (7th Cir. 1996) ("[T]he courtroom is not the place for scientific guesswork, even of the inspired sort."). Furthermore, "[t]he [c]ourt's vigilant exercise of [its] gate-keeper role is critical because of the latitude given to expert witnesses to express their opinions on matters about which they have no firsthand knowledge, and because an expert's testimony may be given greater weight by the jury due to the expert's background and approach." *Loughren*, 604 F. Supp. 2d at 265.

It is well-settled that "damages must be proven with reasonable certainty." *U.S. ex rel. Ervin & Assocs., Inc. v. Hamilton Sec. Group, Inc.*, 370 F. Supp. 2d 18, 55 (D.D.C. 2005). Further, while "methodology is the 'central focus of a *Daubert* inquiry,' . . . a court 'may evaluate the data offered to support an expert's bottom-line opinions to determine if that data provides adequate support to mark the expert's testimony as reliable.'" *Loughren*, 604 F. Supp. 2d at 264 (citation omitted). Such concerns are amplified in the False Claims Act context where damages are trebled. *See U.S. v. Collyer Insulated Wire Co.*, 94 F. Supp. 493, 499 (D.R.I. 1950) (damages in False Claims Act cases cannot be the subject of "speculation and guesswork"). *Daubert* and Federal Rule of Evidence 702 therefore require exclusion of expert testimony on damages if the proposed opinion is based on unreliable assumptions or speculation. *See, e.g.*, *Albert v. Warner-Lambert Co.*, 234 F. Supp. 2d 101, 106-107 (D. Mass. 2002) (excluding expert testimony on damages); *Joy v. Bell Helicopter Textron, Inc.*, 999 F.2d 549, 567-70 (D.C. Cir.

1993) (expert's damages calculation was inappropriate and speculative because it was not properly based on known facts); *In re Air Crash Disaster at New Orleans, La.*, 795 F.2d 1230, 1234-35 (5th Cir. 1986) (same).

ARGUMENT

I. DR. DUGGAN'S CALCULATIONS ARE NOT THE PRODUCT OF RELIABLE PRINCIPLES AND METHODS

A. The Duggan Methodology

Dr. Duggan's methodology is fairly simple. First he simply decides without any basis whatsoever that Dey's WAC should be a quarterly average price net of discounts. To calculate this average, Dr. Duggan and his associates first take a subset of Dey's transactional data that shows sales by Dey to its indirect contract customers. Using this indirect data, Dr. Duggan calculates a net quarterly average price for each NDC of the drugs at issue. This quarterly average price takes the place of Dey's WAC and will be referred to here as the Duggan Dey WAC. Next, Dr. Duggan adds an arbitrary 25% to the Duggan Dey WAC and the resulting number takes the place of the Dey published AWP and will be referred to here as the Duggan Dey AWP. Dr. Duggan then takes the Duggan Dey WAC and the Duggan Dey AWP and plugs them into the various Medicaid and Medicare reimbursement algorithms in place of the published Dey AWP and WACs. He then determines what the reimbursement would have been had the algorithms used the Duggan WAC and AWP instead of Dey's published AWP and WAC. Dr. Duggan then calculates the difference between the reimbursement paid on the claims at issue and the reimbursement that Dr. Duggan claims would have paid had the Duggan Dey WAC and Duggan Dey AWP been reported by First Databank or Redbook. The resulting

difference then becomes the measure of single damages.[1] The steps described above are not based on any reliable principles or methodology and are not supported by any evidence of any kind. Indeed, each step is fatally flawed in one or more ways.

B. Testimony On The Duggan Dey WAC Is Inadmissible

There is no economic analysis that supports the transformation of Dey's WAC to an average quarterly discounted price. WAC is not an average price. Nothing in the term WAC suggests that it is an average price let alone a quarterly average net price. Second, nothing in the term WAC suggests that it is a measure of what providers pay wholesalers for the product. On the contrary, the evidence is undisputed that WAC is an undiscounted invoice price from Dey to its wholesale customers, or, as the federal government has defined it:

> [T]he manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

42 U.S.C. § 1395w-3a. Dr. Duggan ignores the evidence and the government's own view of WAC and instead develops an alternative WAC without any foundation whatsoever.

The Duggan Dey WAC is in fact an alternate version of Dey's Average Manufacturer Price or AMP. As Dr Duggan and his Government employers know, Dey has a contract with the Department of Health, CMS, and all the states that requires Dey to calculate and report the AMP. There is no dispute that Dey has complied with this requirement and submitted to CMS its AMP

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1 In addition to his Duggan Dey WAC and Duggan Dey AWP which are based on average prices, Dr. Duggan also calculates a number of other alternative prices which he chooses not to use in his difference calculations, including the 95 percentile prices for Dey's products for all direct customers, wholesaler direct customers, and pharmacy direct customers. (*See* Duggan Report, Ex. 1, at Table 5). Exhibits to this motion are attached to the Declaration of Marisa A. Lorenzo, filed concurrently, and will be cited herein as "Ex. __".

every quarter for every drug at issue. The AMP is a defined term calculated under CMS's instruction and guidance. It is an quarterly average net discounted price based on Dey transactional data. The Duggan Dey WAC is nothing more than a different version of Dey's AMP.

It is noteworthy that Dr. Duggan had Dey's AMP database but simply ignored it. CMS of course has the Dey AMP so it knows exactly Dey's quarterly average net discounted price on each of its drugs – they do not need Dr. Duggan to tell them that number. In addition, Dr. Duggan's damages assume that Dey would have reported to public databases its quarterly average net discounted price when, in fact, under statute and contract, that price is confidential and cannot be published. (*See* Dey's Rebate Agreement, Ex. 2). Since the quarterly average discounted price cannot be published, it could not enter the reimbursement algorithms, and therefore Dr. Duggan's assumption that reimbursement would have been paid using quarterly average prices is completely unfounded.

C. Testimony On The Duggan Dey AWP Is Inadmissible

To calculate the Duggan Dey AWP, Dr. Duggan simply increases the Duggan Dey WAC by an arbitrary 25%. In other words, he simply assumes that there is a fixed 25% relationship between the AWP and the WAC of Dey's generic drugs. There is absolutely no support for this assumption and Dr. Duggan does not even pretend to offer one. Indeed, Dr. Duggan concedes that the 25% mark-up is not based on any economic analysis or any analysis of Dey or Dey's drugs or the generic business in general, but rather the product of his assumptions in other cases involving other defendants and other drugs.

Dr. Duggan testified that the starting point for his damage opinions in this case were his opinions in the Abbott Texas and federal cases. (Duggan 2/27/09 Dep., Ex. 3, at 320:21-321:2). A comparison of the reports submitted against Abbott and the report submitted in this case

demonstrate that Dr. Duggan's opinions and methodology are substantially the same. In fact, Dr. Duggan was instructed to perform a "find and replace" in the Dey report to remove all references to Abbott. (*See id.* at 325:6-326:4; 321:4-22). The methodology Dr. Duggan created for the Abbott drugs was based on the fact that unlike Dey, Abbott did not report an AWP for much of the time period. In order to create an AWP for Abbott's products, the national compendia added a mark-up to the reported list price. In his Abbott report, Dr. Duggan explains that:

> An examination of the published prices for the Abbott products listed in the Complaint indicates that the AWP is typically 125 percent of the WAC. My own analysis of Abbott's indirect and direct transaction data reveals the difference between the price at which wholesalers and distributors acquire Abbott products and the corresponding price at which they sell the products is on average much less than 25 percent. Despite this, I take the conservative approach of replacing the AWP with 125 percent of the average pharmacy indirect price for each NDC in each quarter . .

(Duggan Abbott Report Ex. 4, at 9). When deposed in the Abbott case, Dr. Duggan confirmed that his use of the 25% was premised on the relationship between the AWPs and WACs in that case, which was driven in part based on a scaling factor used by First DataBank. (*See, e.g.*, Duggan 7/25/08 Dep., Ex. 5, at 614:8-18; Duggan 5/19/09 Dep., Ex. 6, at 299:20-300:10).

When asked why he used the same 25% scaling factor in the Dey case, Dr. Duggan responded that "it is consistent with a scaling factor that I used in my Abbott report." (Duggan 2/26/09 Dep., Ex. 7, at 113:12-15; *see also id.* at 114:1-12). When asked with whom he discussed the scaling factor, Dr. Duggan identified only Plaintiffs' counsel, with the caveat that, "this is stretching back a long way because as I said, this is the same scaling factor that I used in my Abbott report *which was in the works a long time before this.*" (*Id.* at 114:22-115:16) (emphasis added). Here, Dey reported an AWP and WAC for all of the subject drugs and there simply is no basis to use a 25% scaling factor in this case involving an entirely different defendant with different drugs and a different business plan.

There are other facts that underscore the complete lack of any rigorous economic analysis supporting Dr. Duggan's otherwise arbitrary use of a 25% scaling factor. For example, Dr. Duggan testified at his deposition that he considered using a 30% scaling factor because "[t]here was a short period during which the-- Judge Saris issued a ruling talking about a 30 percent speed limit. And I -- I think it is straightforward to -- so that it was partly considering that issue of whether to consider that, that speed limit, speed limit in quotes that she talked about." (Duggan 2/26/09 Dep., Ex. 7, at 115:17-116:3). Dr. Duggan further explained as follows:

> Q. So 130 was not based on any economic analysis that you did?
>
> A. That is, the 130 which is not what I ultimately used, it was not based on -- no. It was not based on economic analysis. It was -- no.
>
> Q. And the 125 is not based on economic analysis either, is it?
>
> A. As I, as I sort of specify in the – as I've tried to specify here, I'm not -- what my report set out to do was to show how the difference, the total Medicaid and Medicare spending would change as a function of these alternative prices. There are an infinite number of possible statistics that one could use. I focused on a number of them in the initial analyses that I believe are informative. The average price. The 95th percentile price, 125 percent of the average which is ensuring that in the vast majority of cases, the Medicaid adjudication algorithm would not reimburse below this average cost, even with their AWP discounts. 125 percent of the average customer pharmacy unweighted, so forth. So I produce a number of different statistics to be transparent. This table 13-B could have gone on for dozens of pages, but the 125 percent was selected with an eye to this, this issue of the Medicaid pharmacy AWP discounts.
>
> Q. But the 125 is not the result of some economic analysis that led you to 125, is it?
>
> A. Well, I believe the analysis that I just described of the state of adjudication algorithms isn't, I would call that an analysis that has been undertaken.

(*Id.* at 120:16-122:5). Parsing Dr. Duggan's evasiveness , it is apparent that the 25% scaling factor is based on conclusions about Abbott drugs and prices coupled with conclusions drawn from this Court's prior opinions indicating a fixed relationship between the WAC and AWP of brand drugs not the generic drugs at issue in this case. As Dr. Hartman, who testified about the relationship between the AWP and WAC of brand drugs, has honestly admitted under oath, there is no economic study or basis for concluding that there is a similar fixed relationship between the WAC and AWP of a generic drug:

> Q. So in terms of -- as far as you know, there isn't a consistent fixed percentage relationship between AWP and WAC on generic drugs, would you agree with that?
>
> A. I have not studied it to know that there is one in the way that there is for innovator drugs.

(Hartman 7/23/09 Dep., Ex. 8, at 328:7-13). Similarly, Dey's expert Dr. Bradford did such an examination for the Dey drugs at issue and found that there was no predictable relationship between AWP and WAC. (*See* Bradford Report, Dkt. 6194, Ex. 1, at 39-40).

Dr. Duggan does not identify any literature or economic analysis to support his view of AWP. Indeed, Dr. Duggan's own academic research and findings undermine his opinion that AWP is based on a quarterly average net discounted price plus 25%. In 2006, shortly before he started working for the Government as an expert witness in AWP litigation, Dr. Duggan and a colleague, Dr. Fiona Scott Morton, published a peer-reviewed article in the influential Quarterly Journal of Economics entitled "The Distortionary Effects of Government Procurement: Evidence From Medicaid Prescription Drug Purchasing."[2] (*See* Ex. 9). In that article, Dr. Duggan described AWP as a "standard industry list price" for brand drugs and AMP as the "average price at which the manufacturer sold the drug" as reported to CMS. (*Id.* at 4-5). In this case, Dr.

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2 In fact, at the Daubert hearing in the Abbott case, Dr. Duggan touted his article as a measure of his reliability. *See* Hearing Tr., December 10, 2009 at 50:14-19.

Duggan abandons his research-based definition of AWP as a standard industry list price and turns it into an average manufacturer price increased by 25%, in the process completely ignoring the AMP. Had Dr. Duggan remained faithful to his academic research and writings, his opinion would say that Dey's AWP is a standard industry price based on the standard list price of the brand and is not an average price at which Dey sells to its customers. Likewise, he would say that if one wanted to see Dey's average manufacturer price, one should look at Dey's AMP because that is the average price that Dey is required to calculate and report. This direct conflict in Dr. Duggan's own academic work requires that his opinions in this case be excluded.

The unreliable nature of the Duggan AWPs are further compounded in the Medicare context where, in addition to substituting the Duggan AWP of Dey, Dr. Duggan also calculates Medicare differences for ipratropium under two additional scenarios where he changes not only the AWPs of Dey in the arrays, but also the AWPs of Roxane. These combined Dey and Roxane scenarios amount to an attempt to multiply damages by inserting flawed Duggan AWPs for two companies. Dr. Duggan has no facts or data to support the substitution of his AWPs for Dey and Roxane in the arrays. Dey and Roxane were sued separately and there are no allegations of conspiracy of collusion in either the Dey or Roxane complaints. Nor are the combined scenarios the product of reliable principles and methods, since Dr. Duggan testified that the only rationale he had for substituting the Duggan AWPs for these two companies was that they had been sued. (Duggan 2/27/09 Dep., Ex. 3, at 434:3-7). The decision to change Dey and Roxane's AWPs in the arrays was therefore an arbitrary one, with no economic rationale. Dr. Duggan has also not performed any analysis of the prices of other manufacturers which appear in the array to determine whether an analysis of the data would reveal prices lower than the AWPs reported in Redbook. (*Id.* at 438:8-15). Dr. Duggan simply assumes that all other manufacturer's AWPs,

including those which are higher than those reported by Dey, are "accurate." These combined scenarios are therefore wholly unreliable.

Dr. Duggan's combined scenarios are also unreliable in that they result in double counting of damages. (*See* Bradford January 15, 2010 letter, Ex. 10, at 2-3). Dr. Duggan has not demonstrated that his Dey and Roxane difference are caused by Dey and Roxane and do not overlap with other manufacturers. For example, in the Administar 2002 Q2 array, when the difference resulting from changing the prices of all other manufacturers except for Dey and Roxane is added to the difference that Dr. Duggan assigns to Dey and Roxane, the total exceeds the Medicare paid amount. (*See* Bradford January 15, 2010 letter, Ex. 10, at 3).

D. Dr. Duggan Ignored Reliable Data Because It Undermines His Conclusions

Dr. Duggan asserts that he is trying to determine the average net prices paid by providers to acquire Dey's drugs from wholesalers. However, even though it was available to him, Dr. Duggan completely ignores the data that has such information, that is, the data from the major wholesalers. (Duggan 2/26/09 Dep., Ex. 7, at 147:19-148:2). Dr. Duggan made the decision not to examine the wholesaler data at all, but to instead rely on Dey's transaction data showing prices that Dey's contract customers agreed to pay Dey. This data does not show what wholesalers charge providers who do not have contracts with Dey for Dey's drugs. Duggan explained his decision to use Dey's data, rather than Cardinal, McKesson, or other wholesaler data, as follows:

> Q. What would be more accurate to give you a better more accurate picture if your objective was to try to find out the average price paid by pharmacists to acquire the Dey drugs? Would the better data set be the average price from the wholesalers or the average -- from the wholesalers to their customers, or the average price that they, that they the company received?
>
> A. I would -- I think it is -- it is my understanding that the Dey indirect transaction data provides very useful information about all

> of their transactions through wholesalers, and whether there are some problems with Dey's data that might cause one to instead focus on a subset of data from some other source, it would be hard for me to speculate, but I use this Dey data in part because it – it summarized all of the Dey indirect transactions, so -- as I said, I'm – I'm, I'm open to the consideration of almost anything in my research and in this report.

(Duggan 2/26/09 Dep., Ex. 7, at 152:10-153:7). The Dey indirect data used by Dr. Duggan cannot capture the ultimate price paid by pharmacies and other providers to wholesalers because Dey did not participate in those transactions.

II. THE FATAL FLAWS IN DR. DUGGAN'S METHODOLOGY ARE COMPOUNDED BY NUMEROUS UNFOUNDED ASSUMPTIONS

The foregoing flaws in Dr. Duggan's opinions are compounded by the fact that he makes numerous assumptions that are unwarranted and are contradicted by the evidence in this case. For example, as set forth above, Dr. Duggan assumes that the Duggan Dey WAC and Duggan Dey AWP would have found their way to the various Medicaid and Medicare reimbursement algorithms. There is no basis for this assumption. Dr. Duggan himself concedes that his opinion rests on the assumption that Dey could have reported the quarterly average net prices:

> Q. So under your methodology, what Dey --what Dey would do if they were using your methodology is come up with the average price and then add 25 percent and then send that into the publication?
>
> * * *
>
> A. My analysis sheds light on how Medicaid and Medicare reimbursement would have changed if these alternative prices have been – have been used. Dey could have reported their average price. They could have reported , you know, other --they could have done many things. They could have reported prices that were more reflective. I have selected one here also trying to give the interested reader a sense of how this varies, how my findings vary as a function of the parameter selected. Had Dey, you know, done something closer to what I described, reported prices that are closer to actual prices, then spending would have fallen.

(Duggan 2/26/09 Dep., Ex. 7, at 123:4-124:7). There is simply no basis to assume that quarterly net discounted prices would be reported to national publications, because under the governing statute and contract between Dey and CMS, the average net price could not be published in the national compendia as it was a confidential number given only to those responsible for running the Medicaid and Medicare programs. (*See* Rebate Agreement, Ex. 2).

Dr. Duggan also assumes that the quarterly net discounted average prices would be used by Medicare and Medicaid even if they could be reported in national compendia:

> Q. We talked about this before the break. But one of your assumptions in this case is that the Medicaid and Medicare programs would have used lower prices of the type that you calculate in your report, correct?
>
> A. I assume Medicaid and Medicare would have used these alternative AWPs, correct.
>
> Q. It's an assumption of your report, right?
>
> A. My analyses calculate, determine, examine, what Medicare and Medicaid would have paid if these alternative AWPs had been in effect.
>
> Q. And they were in fact used?
>
> A. And they were used in adjudicating claims for both programs.

(Duggan 5/19/09 Dep. at 358:16-359:9). Dr. Duggan further stated that his calculations "assume[] that state agencies would have used the AWPs when adjudicating the claims, the alternative AWPs," (Duggan 5/19/09 Dep., Ex. 6, at 345:14-16) and that "if [Defendants] had reported alternative AWPs and they had been published, they would have been used by the DMERCs." (Duggan 2/27/09 Dep., Ex. 3, at 420:14-16).

There is no basis for this assumption. On the contrary, the testimony of those responsible for running the programs refutes Dr. Duggan's assumption. For example, Deidre Duzor, the

Director of the Pharmacy Division for Medicaid at CMS, testified about what would happen if prices similar to the alternative AWPs calculated by Dr. Duggan were used:

> Q. Do you have any opinion about what would be the consequence if the various state Medicaid programs were paying based upon an AWP that was an empirical average of what pharmacies were obtaining drugs for?
>
> A. Well, states don't want to cause access problems any more than the federal government does, so if the new AWPs would turn out to be actual purchasing -- the price at which the drug could be purchased, I think states -- we would have a run on state plan amendments to change their formula for reimbursement.
>
> Q. In what way?
>
> A. To increase it so that -- you know, pharmacies are for-profit businesses. . . .

(Duzor 3/26/08 Dep., Ex. 11, at 904:6-906:5).

There is also overwhelming evidence that reimbursement was not based on paying the lowest prices that Dr. Duggan's opinions contemplate. Throughout the relevant time period in this case, state Medicaid agencies and Medicare officials had access to lower prices, such as WACs, FSS prices, and VA prices, and yet continued to base reimbursement on AWP. In 2000, CMS attempted to implement the DOJ AWPs, lower AWP prices for 32 drugs, including two subject drugs. (Dkt. 6316 at ¶ 17). Plaintiffs admit that for Medicare, these prices were withdrawn, and in Medicaid, 20 states elected not to utilize the lower prices. (Dkt. 6299 at ¶¶ 202, 262). David Tawes, an analyst with the OIG, conducted a survey of state Medicaid personnel regarding their implementation of the DOJ AWPs in connection with the 2001 report, "Medicaid's Use of Revised Average Wholesale Prices." State Medicaid representatives articulated numerous concerns which resulted in their rejection of the lower prices, including concerns that providers could no longer dispense the drugs at that cost, that access would be

jeopardized, and that states needed to look at both AWP and dispensing fees together.[3] (*See e.g.*, Abbott Ex. 143, Ex. 12, at HHD006-364, 453, 367, 336). Dr. Duggan simply ignores this evidence and blithely asserts that he did not research the policy implications and that such analysis was not part of his government assignment in this case:

> Q. Have you done the analysis you believe would be necessary as an economist to provide an expert opinion on whether Medicare and Medicaid would have used the revised prices that you calculate in your report?
>
> A. I would need to think more about this, about that issue. To this point that has not been the thrust of my analysis. But as I said, I did a number of things to gauge the accuracy of that assumption to the extent that the data permitted me. As economists we're not often given all of the data we'd like or all of the variation in the world that we would like. But given the available data and the available variation, I believe that I provided useful information on that issue.

(Duggan 7/14/08 Dep., Ex. 13, at 217:19-218:12).

Dr. Duggan also assumes that dispensing fees would remain constant were his quarterly average net prices used as a basis of reimbursement. Extensive and undisputed evidence demonstrates that this assumption is completely baseless. Ms. Duzor testified that in some cases, paying actual acquisition costs without changing the reimbursement system would limit access:

> Q. Is it fair to say you can think of states where you would not feel comfortable that paying a true acquisition cost with no other changes to the reimbursement system would not be sufficient to ensure access?
>
> A. I don't know where the line would be drawn. But I think that there may be some states that were paying very low dispensing

3 The difficulties in implementing these lower prices for a selected handful of prescription drugs also rebuts the Government's recurring argument that lower prices for Defendant's drugs would not cause access problems for Medicare and Medicaid generally. To the contrary, as evidenced by the high utilization of the drugs at issue in these cases and the concerns articulated regarding the DOJ AWPs, such a change would make a difference to reimbursement policy.

> fees where that would not be adequate reimbursement for a pharmacy.
>
> Q. And would you feel comfortable assuming that a change to paying actual acquisition cost would not have resulted in any change to dispensing fees at any of the state Medicaid programs?
>
> A. No. I think it may have resulted in a change in dispensing fees.

(2/27/07 Duzor Dep., Ex. 14, at 527:11-528:7). State Medicaid witnesses also testified about the need to examine ingredient cost and dispensing fees together. For example, Leo Sullivan, the former Director of Pharmacy Services of Tennessee Medicaid, testified: "the dispensing fee in and of itself is not compensation for what some calculated cost to dispense, that the portion of profit built into the ingredient cost is also a factor in that." (Sullivan Tr., Ex. 15, at 241:4-8). Cody Wiberg, the former Pharmacy Program Manager of Minnesota Medicaid, testified that "if the AWP, on average, was what you would expect most providers to be actually paying for the drug when they purchase it, you would end up raising the dispensing fee, to a certain extent." (Wiberg Tr., Ex. 16, at 169:17-21). The evidence also shows that when states reduce ingredient cost reimbursement, there is often a corresponding increase in dispensing fees. For example, in 2004, California decreased its ingredient cost reimbursement when it changed from an AWP minus 10% to AWP minus 17% methodology. At the same time, it increased the dispensing fee from \$4.05 to \$7.25. (*See* Rosenstein 5/19/09 Dep., Ex. 17, at 188:19-197:2). In 1995, New York decreased its ingredient cost reimbursement from AWP to AWP minus 10%, and increased its dispensing fee from \$2.60 to \$4.50 for brands and \$5.50 for generics. (*See* Mark-Richard Butt 1/26/10 Dep., Ex. 18 at 199:7-202:5).

Another striking example of cross-subsidization occurred with the passage of the Medicare Modernization Act. In 2005, the Medicare ingredient cost reimbursement was decreased from an AWP-based reimbursement to 106% of the Average Sales Price which is

analogous to the Duggan AWP and Duggan WAC. At the same time, the dispensing fee for the inhalation drugs at issue in this case was raised from \$5 to \$57 for the first year, ultimately set at \$33 for a 30-day supply and \$66 for a 60-day supply. See 69 Fed. Reg. 66236, 66425 (Nov. 15, 2004). Dr. Duggan concedes that he assumed the dispensing fee could remain constant and did not take into account evidence to the contrary:

> Q. And in your -- in your analysis that you did here in the Dey report on the Medicare section, you assumed that when you use the average price, in place of the published AWP that the dispensing fee of \$5 would remain in place and it wouldn't go up, correct?
>
> A. Just to clarify, I used 125 percent of the average pharmacy price, which for the reasons that I mentioned earlier, that average pharmacy price tends to exceed the average price for all customers, but it is true that in the analysis that I held other factors constant. So the AWP using the alternative AWPs for the Dey products, how would the allowed amount have changed and how would Medicare reimbursement have changed. And so that is, that should be clear from -- hopefully that's clear from my report.
>
> Q. Well, I didn't see anything in the report about the \$5 dispensing fee that I recall. So my question is are you assuming that when you changed the AWPs, that the dispensing fee that would be paid to the provider would be \$5 and not something higher?
>
> A. That is -- my analysis holds other factors, including that dispensing fee, constant.

(Duggan 2/27/09 Dep., Ex. 3, at 471:9-472:12).

Dr. Duggan similarly assumes that providers would have accepted the lower payments and continued participating in the Medicaid and Medicare programs at the federally required levels. He admits that he did not conduct any analysis to determine pharmacy acceptance of lower reimbursement – a key factor in setting reimbursement. State Medicaid programs are subject to an access requirement that requires that "[t]he agency's payments must be sufficient to enlist enough providers so that services under the plan are available to recipients at least to the

extent that those services are available to the general population." 42 C.F.R. § 447.204 (2009). The record is clear that when states and Medicare have tried to lower the amount paid in reimbursement, pharmacists and other providers have successfully argued that the lower payments would impair access in violation of federal law, and some pharmacies have dropped out of the program. For example, last week, Walgreen's drugstores announced that as of April 16, 2010 they will stop serving Medicaid patients in Washington state, saying that "filling their prescriptions is a money-losing proposition." (*See* Seattle Times Article, Ex. 19).

Opinions that are based on assumption, that have no foundation, and that are not supported by adequate data or analysis simply cannot be admitted. Dr. Duggan's opinions and calculation of damages rest on assumptions that in turn rest on air. Therefore, his opinions and damage calculations cannot be admitted. To allow the jury to hear Dr. Duggan's opinions would prejudice Dey and would impermissibly excuse the Government from meeting its burden of presenting not only a qualified expert, but one whose opinions rest on reliable methodology.

III. <u>THIS COURT SHOULD EXCLUDE DR. DUGGAN'S DIFFERENCES BECAUSE HE HAS USED UNRELIABLE EXTRAPOLATION</u>

Dr. Duggan did not use all the available claim data and plugged holes in the data through extensive extrapolation to arrive at his final Medicaid and Medicare figures. The extrapolation methodology used by Dr. Duggan is similar to the extrapolation he employed in both the Abbott and the Roxane cases and which has been challenged by both Abbott and Roxane.[4] However, there are a few differences which further necessitate the need to exclude Dr. Duggan's opinions.

A. Dr. Duggan's Medicaid Extrapolation

In this case, Dr. Duggan uses a 14 state sample from which to extrapolate, and has calculated approximately $59.4 million in extrapolated damages for the remaining 33 states. The

4 *See* Dkts. 6177; 6975.

14 states in Dr. Duggan's sample were chosen because of their high utilization in terms of total Medicaid spending on NDC-based claims for complaint products. (*See, e.g.*, Duggan Report , Ex. 1, at 31). Dr. Duggan's decision not to use a random sample is only the first problem with his extrapolation. Dr. Duggan does not have claims data for the entire claims period for each of the 14 states. Instead, in many instances, he is using a sample as small as three states from which to extrapolate to the remaining states. For example, from second quarter of 1992 until the third quarter of 1993, Duggan was extrapolating from a selected sample of only Illinois and New Jersey. In fact, in only four years, 2001-2004, did Duggan have state level claims data for all 14 states. (*See, e.g.*, Duggan Report, Ex. 1 at Figures 13A-26A).

Dr. Duggan's Medicaid extrapolation is full of errors and is unreliable. Dey's expert, Dr. Bradford, has examined all of the available state level claims data and has quantified the errors resulting from Dr. Duggan's extrapolation. However, even Dr. Duggan himself has admitted that his differences are overstated. On November 30, 2009, Dr. Duggan submitted an analysis of an additional 16 states' claims data. (Duggan 11/30/09 Letter, Ex. 20). The chart provided by Dr. Duggan shows that when Alabama is included in his analysis, the average error rate is 10.19%.[5] *Id.* Furthermore, when separated out on a state by state level, the error rate is startling, reaching as high as 36.57%. *Id.* These results show that Dr. Duggan's extrapolation is unreliable. His assessment of the variability of the states was incorrect, leading to wildly differing damages once the claims data, which he had in his possession all along, was examined. The error rates across states cannot be averaged to result in a lower error rate, because the jury will need to examine liability and damages on a state by state basis.

5 There is no reasonable basis to exclude Alabama from the calculation.

Dr. Duggan has also provided another indicia of the unreliability in the form of his confidence intervals. (*See* Dugan February 5, 2010 letter, Ex. 21). Dr. Duggan's claims that in the Dey case, there is a "90% probability the true federal difference is between $55.274 million and $63.550 million, and with 95% probability it is between $54.497 million and $64.328 million." (*Id.* at 4). Even assuming a confidence interval is appropriate here, Dr. Duggan's makes several errors in calculating his "confidence interval."[6] Correcting for these errors almost doubles Dr. Duggan's "confidence interval" to +/- $10.03 million, suggesting a margin of error of roughly +/- 17%. (*See* March 17, 2010 Letter of Dr. Bradford, Ex. 22, at Point 3). This, however, likely understates the true error rate in his calculations, given the inflation detected in his extrapolations compared with claims data. (*Id.*).

In addition, Dr. Duggan's extrapolation within the states is unreliable because Dr. Duggan does not evaluate various factors influencing how a particular state paid for Medicaid drugs changed over time. For instance, if a state changes its reimbursement policy by switching to a different formula, implementing a MAC, or paying more frequently based on a U&C, the ratio of claims with a "difference" greater than zero would also change, as would the payment bases for those claims. Yet Dr. Duggan conducted no analysis of how these changes would affect his extrapolated differences.

B. Dr. Duggan's Medicare Extrapolation Is Inadmissible

Dr. Duggan's Medicare extrapolation is unreliable because he calculates differences for quarters where he does not have arrays from the DMERCs. Of the approximately $208 million

6 Dr. Duggan makes three errors which cause him to overstate the precision of his extrapolations. First, the program used by Duggan to calculate his standard deviation has an error in coding that artificially deflates his standard deviation. Second, Duggan ignores the variation of the error term. Third, Duggan assumes that the variables are uncorrelated without proving any basis for it. (*See* March 17, 2010 Letter of Dr. Bradford, Ex. 22, at Point 3).

in ipratropium Medicare damages calculated by Dr. Duggan in the Dey-only scenario, over $33 million are calculated from quarters where Dr. Duggan does not have an array. Dr. Duggan does not have an array for DMERC A until 1999 Q3, yet he calculates over $7 million of damages for the nine previous quarters. The evidence before this Court demonstrates that the DMERCs did not always put the same products in the arrays, and that the differences between the arrays has an effect on the median determination. It is therefore unreliable for Dr. Duggan to extrapolate damages for those quarters in which he does not have arrays.[7]

CONCLUSION

For the reasons set forth herein, this Court should grant Dey's Motion to Exclude the Opinions of Mark Duggan, Ph.D.

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Respectfully Submitted,

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7 It may be noted that following the motion *in limine* for Duggan in the Abbott case, the DOJ withdrew the Medicare extrapolation in that case. *See* Dkt. 6897.

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on March 22, 2010, a copy to LexisNexis File and Serve for posting and notification to all parties.

By: /s/ William A. Escobar